September 19, 1973

Dr. Gerald D. Laubach
President
Pfizer Inc.
235 East 42nd Street
New York, New York 10017

Dear Dr. Laubach,

I am very grateful to you for taking time to reply by your letter of August 23rd to my academic inquiries. I enjoy the opportunity to read the material you sent me; perhaps inevitably it does not quite go to the heart of the problem, namely the shrewdness of your own analysis of the contingencies that a drug might face in the course of its development.

The bureaucratic irrationalities of the FDA procedures have elicited such an angry, emotional response among some of my friends in the pharmaceutical industry that I wondered whether this may not also have clouded their judgment about making the most effective empirical adjustments to the real situation. I was interested in developing a point of view about the possible costs, as well as conceivable benefits, that may stem from the last decade pattern of FDA regulations. To the extent that the industry fails to internalize the constraints, however irrational they may be, that they may face in seeking drug approval they may continue to make large investments in drug development without adequately anticipating the actual problems they will face in seeking approval. I was simply conjecturing that this might be a problem, and I was struck by the remark attributed to you by Business Week that your own batting average at ~~Kaiser~~ Pfizer had been remarkably high. If so, this then means that you have policies for accommodating to the existing system which are pragmatically more successful than applies to others. One might then argue that the social cost of the regulatory framework is amplified by your less insightful colleagues' failure to make the most efficient accommodation to the real world. Your remark that your "loss of candidates after completion of Phase II clinical trials has been a rarity" probably does speak to a remarkable degree of insight and judgment on your part. This being the case, it is easy to sympathize with your focus on irrational delay rather than inadequately predicted refusal as your main problem with the agency.

Well, we might all be hopeful that there may be some change in the texture of the FDA's bureaucratic process during the current period. Certainly it is a very important policy consideration to focus on the issue of bureaucratic implementation rather than the basic validity of the current law as the major problem that you face. To that extent arguments like those

of Sam Peltzmann that we ought to do away with the FDA altogether are probably really not very helpful.

Sincerely yours,

Joshua Lederberg
Professor of Genetics

JL/rr